

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

**IN RE: PHILIPS RECALLED CPAP,
BI-LEVEL PAP, AND MECHANICAL
VENTILATOR PRODUCTS
LITIGATION**

This Document Relates to:

Consolidated Second Amended Class
Action Complaint for Medical Monitoring
(ECF No. 815)

:
: Master Docket: No. 21-mc-1230-JFC
:
: MDL No. 3014
:
:
:
:
:
:
:
:
:
:

**PHILIPS RS NORTH AMERICA LLC'S RESPONSES TO OBJECTIONS TO THE
REPORT AND RECOMMENDATION ON THE MOTION TO DISMISS THE SECOND
AMENDED CLASS ACTION COMPLAINT FOR MEDICAL MONITORING**

John P. Lavelle, Jr. (PA54279)
john.lavelle@morganlewis.com
Lisa C. Dykstra (PA67271)
lisa.dykstra@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
2222 Market Street
Philadelphia, PA 19103-3007
Tel: 215.963.5000

Wendy West Feinstein (PA86698)
wendy.feinstein@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Center, 32nd Floor
Pittsburgh, PA 15219-6401
Tel: 412.560.3300

*Counsel for Defendant Philips RS North
America LLC*

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. ARGUMENT	2
A. THE DISPUTED JURISDICTIONS REQUIRE ALLEGATIONS OF PRESENT PHYSICAL INJURY.	2
B. PLAINTIFFS FAIL TO ALLEGE PRESENT PHYSICAL INJURY.	5
C. THE R&R CORRECTLY ANALYZED STATE LAW.	8
III. CONCLUSION	9

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	5
<i>Baker v. Croda Inc.</i> , No. 21-3360, 2022 WL 19010312 (3d Cir. Oct. 21, 2022).....	4
<i>Baker v. Croda Inc.</i> , No. 393, 2022, 2023 WL 5517797 (Del. Aug. 24, 2023)	3, 4
<i>Bernier v. Raymark Indus., Inc.</i> , 516 A.2d 534 (Me. 1986).....	7
<i>Berry v. City of Chic.</i> , 181 N.E.3d 679 (Ill. 2020)	3
<i>Brown v. Saint-Gobain Performance Plastics Corp.</i> , 300 A.3d 949 (N.H. 2023)	3
<i>City of Phila. v. Lead Indus. Ass’n, Inc.</i> , 994 F.2d 112 (3d Cir. 1993).....	<i>passim</i>
<i>Donovan v. Philip Morris USA, Inc.</i> , 914 N.E.2d 891 (Mass. 2009)	6, 7
<i>Dougan v. Sikorsky Aircraft Corp.</i> , 251 A.3d 583 (Conn. 2020)	7
<i>Dumontier v. Schlumberger Tech. Corp.</i> , 543 F.3d 567 (9th Cir. 2008)	6
<i>Erie Railroad Co. v. Tompkins</i> , 304 U.S. 64 (1938).....	2, 3, 4
<i>Henry v. Dow Chem. Co.</i> , 701 N.W.2d 684 (Mich. 2005).....	3
<i>Lowe v. Philip Morris USA, Inc.</i> , 183 P.3d 181 (Or. 2008)	3
<i>Metro-N. Commuter R. Co. v. Buckley</i> , 521 U.S. 424 (1997).....	3

<i>Parker v. Wellman</i> , 230 F. App'x 878 (11th Cir. 2007)	6
<i>Pounders v. Enserch E & C, Inc.</i> , 306 P.3d 9 (Ariz. 2013).....	7
<i>Rainer v. Union Carbide Corp.</i> , 402 F.3d 608 (6th Cir. 2005)	6
<i>In re Rezulin Prod. Liab. Litig.</i> , 361 F. Supp. 2d 268 (S.D.N.Y. 2005).....	6
<i>Sondag v. Pneumo Abex Corp.</i> , 55 N.E.3d 1259 (Ill. App. Ct. 2016)	6, 8
<i>Tatel v. Mt. Lebanon Sch. Dist.</i> , 637 F. Supp. 3d 295 (W.D. Pa. 2022).....	6
<i>Travelers Indem. Co. v. Dammann & Co.</i> , 594 F.3d 238 (3d Cir. 2010).....	2, 4, 8
<i>In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.</i> , No. 19-2875, 2023 WL 1818922 (D.N.J. Feb. 8, 2023)	4, 5
<i>Walston v. Boeing Co.</i> , 334 P.3d 519 (Wash. 2014).....	7
<i>Wood v. Wyeth-Ayerst Lab'ys, Div. of Am. Home Prod.</i> , 82 S.W.3d 849 (Ky. 2002)	3
Other Authorities	
<i>Restatement (Second) of Torts</i> § 7 cmt. B (1965).....	8
<i>Restatement (Second) of Torts</i> § 15 cmt. A (1965).....	8

Philips RS North America LLC (“Respironics”) respectfully submits these responses to Plaintiffs’ Objections (“Plaintiffs’ Objections” or “Pls. Objs.”) (ECF No. 2314) to the Report and Recommendation (the “R&R”) (ECF No. 2273) on Respironics’ motion to dismiss Plaintiffs’ medical monitoring complaint (“MM Master Complaint”) (ECF No. 815). Plaintiffs’ Objections should be overruled, and this Court should adopt the R&R except as to those points raised in Respironics’ Objections (ECF No. 2316).

RESPIRONICS’ RESPONSES TO PLAINTIFFS’ OBJECTIONS

I. INTRODUCTION

Plaintiffs object to the recommended dismissal of their claims asserted under the laws of 28 jurisdictions (the “Disputed Jurisdictions”), in which the states’ highest courts have not adopted an exception to the traditional tort law requirement to allege a present physical injury as a prerequisite to any relief, including medical monitoring.¹ The R&R found that Third Circuit precedent requires the Court to predict that the highest courts of the Disputed Jurisdictions would adhere to the present physical injury requirement because federal district courts may not expand tort liability under state law. The R&R further found that Plaintiffs fail to allege present physical injury and seek only damages associated with the risk of future injury. The R&R accordingly concluded that Plaintiffs fail to state claims for medical monitoring relief under the laws of the Disputed Jurisdictions, requiring dismissal of Plaintiffs’ claims in those jurisdictions.

Plaintiffs object that: (1) the R&R incorrectly concluded that the Disputed Jurisdictions require allegations of a present physical injury, and (2) even if there is such a requirement,

¹ The R&R recommends dismissal under the laws of 30 jurisdictions: Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, Texas, Virginia, and Washington. Plaintiffs do not object to the dismissal of all claims under the laws of North Carolina and New Hampshire. Pls. Objs. at 2 n.2.

Plaintiffs’ conclusory assertion of “sub-cellular change” satisfies it. The R&R’s recommendation is grounded in controlling Third Circuit precedent and the laws of the Disputed Jurisdictions, and Plaintiffs’ Objections should be overruled.

II. ARGUMENT

A. The Disputed Jurisdictions Require Allegations of Present Physical Injury.

Plaintiffs agree that under *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), state substantive law governs whether they must plead a present physical injury, and where there is ambiguity in state law, the Court’s task is to predict how the state’s highest court would decide the issue. Pls. Objs. at 1, 7. It is undisputed that neither the intermediate appellate nor the highest courts of the Disputed Jurisdictions have carved an exception to the present physical injury requirement for claims seeking medical monitoring. Nevertheless, Plaintiffs object to the R&R because it rejected their invitation to expand liability under state law by predicting that the highest courts of the Disputed Jurisdictions would create such an exception. *Id.* at 7-8.

The R&R correctly recognized that Third Circuit precedent precludes Plaintiffs’ argument. *See* R&R at 6-7; *Travelers Indem. Co. v. Dammann & Co.*, 594 F.3d 238, 244 (3d Cir. 2010) (predicting the New Jersey Supreme Court would apply the economic loss doctrine to a product liability crossclaim as that is “the interpretation that restricts liability, rather than expands it”). District courts may not engraft onto state law “exceptions or modifications which may commend themselves to the federal court” but have not been adopted by state appellate courts. R&R at 6 (quoting *Day & Zimmermann, Inc. v. Challoner*, 423 U.S. 3, 4 (1975) (per curiam)). “Federalism concerns require that [district courts] permit state courts to decide whether and to what extent they will expand state common law.” *Id.* (quoting *City of Phila. v. Lead Indus. Ass’n, Inc.*, 994 F.2d 112, 123 (3d Cir. 1993)). Accordingly, district courts should “opt for the interpretation [of state law] that restricts liability” in the absence of “clear authority” in state law favoring an exception

that “expands it.” *Travelers*, 594 F.3d at 250, 253; *City of Phila.*, 994 F.2d at 115 (“[W]e may not significantly expand state law without a clear indication that the Pennsylvania Supreme Court would do the same.”). “Clear authority” for an expansion of state law liability may not be found in state trial court decisions, federal district courts’ *Erie* predictions that “jum[p] ahead of the current state of [the relevant state’s] law,” a “split of authority among the highest state courts,” or “policy arguments.” *City of Phila.*, 994 F.2d at 125-26, nn.12, 13 (refusing to predict that Pennsylvania would expand liability by adopting market share liability in the absence of a “clear indication” that the Pennsylvania Supreme Court would do so).

The obligation to allege a present physical injury is a “traditional” prerequisite to stating a viable tort claim, irrespective of the type of relief sought. R&R at 4, n.3.² The R&R acknowledges this and that some states have created an exception to the rule or created an independent medical monitoring cause of action, and that there are policy reasons why a state may decide to abandon the traditional rule. But the R&R correctly concludes that the Disputed Jurisdictions all adhere to this traditional rule, and that there is no authority from which the Court could predict any of these jurisdictions would carve an exception for medical monitoring relief. R&R at 6-9. Third Circuit

² Numerous courts, including the U.S. Supreme Court, have recognized that the traditional rule requires a plaintiff to allege a present physical injury to state a cause of action in tort. *See Metro-N. Commuter R. Co. v. Buckley*, 521 U.S. 424, 441 (1997) (recognizing that present physical injury is a traditional tort requirement and only a few states had carved an exception to this rule for claims seeking medical monitoring); *Baker v. Croda Inc.*, No. 393, 2022, 2023 WL 5517797, at *3 (Del. Aug. 24, 2023) (“[C]laims in tort require an actual or imminent injury. To hold otherwise would constitute a significant shift in our tort jurisprudence.”); *Brown v. Saint-Gobain Performance Plastics Corp.*, 300 A.3d 949, 952 (N.H. 2023) (refusing to abandon the traditional “physical injury rule”); *Berry v. City of Chic.*, 181 N.E.3d 679, 688-89 (Ill. 2020) (“the traditional understanding of tort law” requires manifested “harm” that is not satisfied by the purported need for “diagnostic medical testing” following exposure); *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 689 (Mich. 2005) (rejecting call for medical monitoring exception “to the rule that a present physical injury is required”); *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 184 (Or. 2008) (affirming present physical injury rule); *Wood v. Wyeth-Ayerst Lab’ys, Div. of Am. Home Prod.*, 82 S.W.3d 849, 852 (Ky. 2002) (“[A] cause of action in tort requires a present physical injury[.]”).

precedent therefore prohibits the Court from predicting they would, because to do so impermissibly would expand liability under state law, as explained in the R&R. R&R at 4, 6-9.

Plaintiffs’ objection ignores Third Circuit precedent. Relying solely on an unpublished class certification decision in *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, No. 19-2875 (RBK/SAK), 2023 WL 1818922 (D.N.J. Feb. 8, 2023), Plaintiffs urge the Court instead to apply a “flexible policy” and make an *Erie* prediction that abandons the present physical injury requirement in “states that lack a definitive state court ruling” because the “right to plead medical monitoring claims” “involves a decision on substantive, not procedural, state law.” Pls. Objs. at 7-8 (quoting *Valsartan*, 2023 WL 1818922 at *26 n.31, 68 (App.)). The Court should reject Plaintiffs’ objection for several reasons.

First, Plaintiffs’ obligation to plead a present physical injury is a substantive state law issue governed by *Erie*, not a procedural issue controlled by the Federal Rules of Civil Procedure. *See Baker v. Croda Inc.*, No. 21-3360, 2022 WL 19010312, at *3 (3d Cir. Oct. 21, 2022) (holding the need to allege a present physical injury is governed by state law and certifying question to the Delaware Supreme Court). Plaintiffs admit this in their objections. Pls. Objs. at 7.

Second, the present physical injury requirement exists to curb “unlimited and unpredictable liability.” *Baker*, 2023 WL 5517797, at *2 (quoting *Buckley*, 521 U.S. at 442). The Court may not predict that the highest courts of the Disputed Jurisdictions would abandon the requirement absent a clear indication from those courts themselves, because to do so would expand medical monitoring liability under state law. *Travelers*, 594 F.3d at 253; *City of Phila.*, 994 F.2d at 115. Plaintiffs fail even to mention *Travelers* in their objections and fail to explain why the holdings of *Travelers* and *City of Philadelphia* are not controlling here.

Third, Plaintiffs’ reliance on a district court’s decision in *Valsartan* is misplaced—the

decision is not controlling and cannot overcome the result required by Third Circuit precedent. Even if *Valsartan* were persuasive authority, it is inapposite because there the district court did not substantively decide whether any of the Disputed Jurisdictions requires allegations of present physical injury. Instead, the *Valsartan* decision resolved only the plaintiffs’ motion for *class certification*—not a motion to dismiss—and addressed only whether variations in state law created individual inquiries that precluded use of class procedures.

The *Valsartan* district court found that deciding the procedural class certification question did not require it to resolve any questions of state substantive law, including whether any given state adheres to the traditional physical injury requirement. Instead, the *Valsartan* court reasoned it needed only to determine whether the state substantive law issues were common among state sub-class members and could be resolved on a class-wide basis. *Valsartan*, 2023 WL 1818922 at *33, 36; *see also id.* at *68 (explaining in notes discussing Alaska that “class certification is NOT a liability ISSUE”) (emphasis in original). *Valsartan* therefore does not speak to the issue presented by Defendants’ motion and offers Plaintiffs no assistance.

B. Plaintiffs Fail to Allege Present Physical Injury.

Plaintiffs further object that even if the R&R correctly found that the Disputed Jurisdictions require present physical injury, their conclusory allegations that using the recalled devices caused them to experience “subcellular or other physiological changes” satisfies that requirement. Pls. Objs. at 2. Plaintiffs’ contention is incorrect and should be rejected.

First, the R&R correctly disregarded Plaintiffs’ allegations of “physiological change” because they are conclusory statements unsupported by well-pled factual allegations. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (holding Rule 8 requires courts to disregard “threadbare recitals . . . supported by mere conclusory statements”). The MM Master Complaint alleges no facts describing this “change,” what Plaintiffs mean by “subcellular,” whether or how any such

“change” has caused any Plaintiff present physical impairment, how the alleged “change” indicates increased risk of any particular disease, the extent/severity of this increased risk, or why the risk necessitates medical monitoring. In the absence of any well-pled factual allegations, the R&R correctly disregards Plaintiffs’ “subcellular or other physiological change” formulation. *See Tatel v. Mt. Lebanon Sch. Dist.*, 637 F. Supp. 3d 295, 308 (W.D. Pa. 2022), *clarified on denial of reconsideration*, No. CV 22-837, 2023 WL 3740822 (W.D. Pa. May 31, 2023) (Conti, J.).

Second, Plaintiffs posit that asymptomatic “physiological change” is generally recognized as constituting a present physical injury, which Plaintiffs claim is supported by *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901 (Mass. 2009) and the definition of “Bodily Harm” in the *Restatement (Second) of Torts* § 15. Pls. Objs. at 6-7. Plaintiffs are wrong.

“All life is change, but all change is not injurious.” *Dumontier v. Schlumberger Tech. Corp.*, 543 F.3d 567, 570 (9th Cir. 2008). Physical injury means a practical, functional impairment of the body’s functions. *Sondag v. Pneumo Abex Corp.*, 55 N.E.3d 1259, 1264-65 (Ill. App. Ct. 2016). Plaintiffs’ conclusory allegation of mere “subcellular or other physiological change” alleges no such present impairment. *See Rainer v. Union Carbide Corp.*, 402 F.3d 608, 621 (6th Cir. 2005) (“Accepting the plaintiffs’ claim would [] throw open the possibility of litigation by any person experiencing even the most benign subcellular damage.”) (applying Kentucky law). That is by design—the medical monitoring relief Plaintiffs seek is premised on costs allegedly necessitated by an increased risk of *future harm*. Otherwise, Plaintiffs would have simply filed personal injury claims. Increased risk of contracting a *future* illness or injury is not a *present*

physical injury, a self-evident proposition that numerous courts have recognized.³

Plaintiffs’ theory that medical monitoring claims may be premised on “subcellular or other physiological changes” derives from a single decision of the Massachusetts Supreme Judicial Court, *Donovan*, 914 N.E.2d at 901, which has not been adopted by the highest court of *any* other state. Not even this solitary outlier decision supports Plaintiffs’ assertion that they have adequately alleged present physical injury in the Disputed Jurisdictions. *City of Phila.*, 994 F.2d at 125-26, n.12. In *Donovan*, the plaintiffs alleged “objectively observable and identifiable damage to the tissues and structures of their lungs resulting in a substantially increased risk of cancer” requiring “medical monitoring.” 914 N.E.2d at 898. The court held that this observable damage and “attendant substantial increase in risk of cancer” may “establish the elements of injury and damages,” but only for a claim for future medical monitoring expenses, not “the full range of tort damages.” *Id.* at 901. The court expressly acknowledged that it was *not* requiring “manifested” “physical harm.” *Id.* at 900-01. Instead, *Donovan* created a “stand-alone medical monitoring cause of action for . . . subclinical injuries,” which has not been followed by numerous courts because the present physical injury requirement demands manifest physical harm. *See Dougan v. Sikorsky Aircraft Corp.*, 251 A.3d 583, 592, 593 n.16 (Conn. 2020) (collecting authorities).

Plaintiffs’ invocation of *Restatement (Second) of Torts* § 15 also is misplaced. Section 15

³ *See, e.g., Parker v. Wellman*, 230 F. App’x 878, 882 (11th Cir. 2007) (rejecting assertion that cellular damage constitutes “a current physical injury under Georgia law”); *In re Rezulin Prod. Liab. Litig.*, 361 F. Supp. 2d 268, 273-78 (S.D.N.Y. 2005) (allegations of subcellular mitochondrial damage insufficient to establish present physical injury under Louisiana and Texas law); *Walston v. Boeing Co.*, 334 P.3d 519, 522 (Wash. 2014) (“[A]symptomatic cellular-level injury . . . is not itself a compensable injury”) (citations omitted); *Pounders v. Enserch E & C, Inc.*, 306 P.3d 9, 14 (Ariz. 2013) (until “the disease is discoverable . . . a legally compensable injury does not exist” “based on subcellular injuries occurring at exposure”); *Bernier v. Raymark Indus., Inc.*, 516 A.2d 534, 543 (Me. 1986) (“[M]icroscopic injury . . . is ‘insufficient to constitute the actual loss or damage . . . required . . . under generally applicable principles of tort law.’”) (citations omitted).

defines “Bodily Harm” as a “physical impairment,” and then states that an alteration in the structure or function of any part of the body—even if it “causes no other harm”—is an impairment. *Restatement (Second) of Torts* § 15 cmt. A (1965). Section 15, however, appears in Chapter 2, which addresses the intentional tort of *battery*, which requires only an offensive “touching” to establish liability even if the “touching” does no damage. *Sondag*, 55 N.E.3d at 1265. Negligence and strict liability claims are different; “physical harm” is a required element. *Id.* at 1263, 1265. “Harm” means “loss or detriment to a person, and not a mere change or alteration in some physical person.” *Restatement (Second) of Torts* § 7 cmt. B (1965); *Sondag*, 55 N.E.3d at 1265. Asymptomatic physiological change that does not cause “physically impairing loss or detriment to” the plaintiff does not satisfy the requirement to allege physical harm. *Sondag*, 55 N.E.3d at 1264 (“[W]e do not see how these conditions [asymptomatic pleural plaques and interstitial fibrosis] have affected [Sondag] in any practical, functional way.”).

The R&R, therefore, correctly reduces Plaintiffs’ argument to an assertion “that the economic loss associated with diagnostic testing necessitated by another’s tortious conduct is a sufficient injury to support a medical monitoring claim.” R&R at 5. And it correctly concludes that Third Circuit precedent, including *Travelers* and *City of Philadelphia*, does not allow the Court to accept Plaintiffs’ “economic loss” argument because it would significantly expand tort liability in the Disputed Jurisdictions without sufficient state law support. R&R at 6-9.

C. The R&R Correctly Analyzed State Law.

Finally, Plaintiffs argue that the R&R incorrectly interpreted the law of each of the Disputed Jurisdictions and incorporate over eighty pages of case tables that Plaintiffs had originally submitted with their briefing before the Special Master. Pls. Objs. at 9-15, Exs. A-C (ECF Nos. 2314-1-3). For ease of reference, Respironics summarizes in Appendix A hereto the relevant excerpts of case tables and discussion of cases included in its briefing before the Special

Master.

Plaintiffs identify no error in the R&R's analysis of the various state authorities. For all the reasons explained above, the lower state court and federal district court opinions Plaintiffs mistakenly rely upon cannot alter the result required by Third Circuit precedent, and the R&R correctly concluded that Plaintiffs have identified no authority that would support an expansion of state tort law liability for claims seeking medical monitoring. *See City of Phila.*, 994 F.2d at 115.

III. CONCLUSION

For the foregoing reasons, those stated in Respironics' Motion (ECF No. 1352) and Reply (ECF No. 1828), at oral argument, and in Respironics' limited objections to the R&R, Respironics respectfully requests that this Court overrule Plaintiffs' Objections and adopt the recommendation to dismiss the claims asserted under the laws of the Disputed Jurisdictions.

Dated: November 30, 2023

Respectfully Submitted,

/s/ John P. Lavelle, Jr.

John P. Lavelle, Jr. (PA54279)

john.lavelle@morganlewis.com

Lisa C. Dykstra (PA67271)

lisa.dykstra@morganlewis.com

MORGAN, LEWIS & BOCKIUS LLP

2222 Market Street

Philadelphia, PA 19103-3007

Tel: 215.963.5000

Wendy West Feinstein (PA86698)

wendy.feinstein@morganlewis.com

MORGAN, LEWIS & BOCKIUS LLP

One Oxford Center, 32nd Floor

Pittsburgh, PA 15219-6401

Tel: 412.560.3300

*Counsel for Defendant Philips RS North
America LLC*

CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2023, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.